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EXAMINER KIMBALL, JEREMIAH T				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Office Action Summary

Application No.

10/568,090

Applicant(s)

SUN ET AL.

Examiner

Jeremiah T. Kimball

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment after non-final 31 December 2008. Examiner acknowledges Applicant's amendment. **Claims 1-21 are active.**

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. **Claims 1-3, 5, 7, 10, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Heilman et al. (US 6,066,085), hereinafter Heilman.**
4. In regards to **claim 1**, Heilman discloses a blood pump actuator (i.e. apparatus 10) to generate a driving force for driving a blood pump, the blood pump actuator comprising: a motor unit (i.e. electric servo-motor 56) having a stator 58 and a rotor 60, and rotating to generate a rotating force; a cam unit (i.e. cam 52, cover 49, eccentric shaft 47) to convert the rotating motion of the motor unit into a rectilinear reciprocating motion; and a bellows unit 20 comprising a bellows, which is expandable and contractible and contains a fluid therein, and an upper bellows plate (i.e. flat base plate 15) and a lower bellows plate (i.e. movable plate 28) respectively attached to the upper and lower ends of the bellows, wherein the lower bellows plate moves upwards and downwards in a vertical direction according to the rectilinear reciprocating motion of the cam unit engaging with the lower bellows plate, and the bellows repeatedly expands and contracts according to the vertical movement of the lower bellows plate (Col. 4, Line 5 – Col. 5, Line 39; Col. 9, Lines 40-51; Col. 11, Lines 1-28; Fig. 1, 2, and 13).

Furthermore, Heilman's device inherently provides a fluidic pressure output to drive the blood pump considering the closed volume of the bellows 20 operates based on the mechanical means compressing and expanding an enclosed compartment, creating air pressure changes that drive fluid in and out of the bellows.

5. In regards to **claim 2**, Heilman discloses the device according to claim 1, wherein the cam unit comprises: a cam 52 having a cam guide (i.e. cam follower 45) continuously formed around an outer circumferential surface of a cylindrical body of the cam; a cam cover 49 mounted to an upper end of the cam; and a cam gear (i.e. eccentric shaft 47) mounted to an end of the cam cover such that the cam gear is concentric with the cam and receives the rotating force of the motor unit (Col. 12, Lines 1-37; Fig. 14 and 15).

6. In regards to **claim 3**, Heilman discloses the device of claim 2, wherein the bellows unit is placed on the upper end of the cam unit, and the lower bellows plate comprises a lower bellows plate extension part (i.e. part of the pumping arm 33) which extends, at an edge of the lower bellows plate, towards the cam unit, is perpendicular to the lower bellows plate, is spaced apart from the cam unit, and is placed outside the cam unit, wherein the lower bellows plate extension part comprises a cam guide engagement part 43 provided on an inner surface thereof to engage with the cam guide (Col. 12, Lines 6-37; Fig. 14).

7. In regards to **claim 5**, Heilman discloses the device of claim 3, wherein the cam guide 45 comprises a depressed cam guide, while the cam guide engagement part 43 comprises a protruding cam guide engagement part (Fig. 14).
8. In regards to **claim 7**, Heilman discloses the device of claim 3, wherein the cam guide 45 has an asymmetrical curve shape (Fig. 14).
9. In regards to **claim 10**, Heilman discloses the device of claim 3, wherein the lower bellows plate extension part is continuously formed around an outer circumferential surface of the lower bellows plate (Fig. 14).
10. In regards to **claim 15**, Heilman discloses the device of claim 1, further comprising: a reduction gear mechanism (i.e. speed or planetary gear reducer 70) placed between the motor unit and the cam unit (Col. 11, Line 29 – Col. 12, Line 5; Fig. 14 and 18).
11. In regards to **claim 16**, Heilman discloses the device of claim 15, wherein the reduction gear mechanism comprises a planetary gear mechanism unit (Col. 11, Line 29 – Col. 12, Line 5; Fig. 14 and 18).
12. In regards to **claim 17**, Heilman discloses the device of claim 16, wherein the planetary gear mechanism comprises: a sun gear (i.e. output shaft 62) having a gear part around an outer circumferential surface thereof; a carrier (i.e. within rotor portion 60) placed at a predetermined height different from a height of the gear part of the sun gear; at least two or more planetary gears 72, 74, 76, 78 mounted on a surface of the carrier and engaging with the gear part of the sun gear; and a ring gear (i.e. internal ring gear 68) having a gear part around an inner circumferential surface thereof and

engaging with the planetary gears, wherein the carrier is mounted to an inner surface of the rotor, the sun gear is concentric with the cam unit, and the ring gear is integrally formed with the cam gear (Col. 11, Line 29 – Col. 12, Line 5; Fig. 14 and 18).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman.

15. In regards to **claim 4**, Heilman teaches the device of claim 3 except wherein the cam guide comprises a protruding cam guide, while the cam guide engagement part comprises a depressed cam guide engagement part. The feature of having a protruding cam guide with a depressed cam guide engagement part would have been a matter of obvious design choice to one of ordinary skill in the art at the time of invention since Applicant has asserted no specific purpose, nor any inherent advantage in the claimed

shape, and one of ordinary skill in the art would be inclined to choose various shapes based on suitability of purpose, absent criticality or unexpected results.

16. **Claims 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman in view of Murakami et al. (US 5,655,953), hereinafter Murakami.**

17. In regards to **claim 6**, Heilman discloses the device of claim 3, except wherein the cam guide has a sine curve shape. Attention is directed to the secondary reference of Murakami, which discloses a manufacturing method for a wave cam (i.e. with a sine curve shape cam guide) for a compressor (e.g. a main component in blood pumps). Murakami's manufactured cam produces axial displacement of a point as a result of one rotation of the wave cam following the wave cam surface (i.e. cam guide) having the shape of a double cycle sine wave curve (Col. 1, Lines 38-56; Fig. 3). Heilman and Murakami are concerned with the same field of endeavor, namely the design of wave cam plate type compressors which reciprocate a body by rotating a wave cam integrally attached to a drive shaft. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Heilman by incorporating a compressor with a sine curve-shaped cam guide, as taught by Murakami, within a blood pump actuator to produce the axial displacement necessary to fill and collapse a bellows.

18. In regards to **claim 8**, Heilman in view of Murakami teaches the device of claim 3 except wherein the cam guide has a stepped shape. The feature of having a stepped-shaped cam would have been a matter of obvious design choice to one of ordinary skill in the art at the time of invention since Applicant has asserted no specific purpose, nor

any inherent advantage in the claimed shape, and one of ordinary skill in the art would be inclined to choose various shapes based on suitability of purpose, absent criticality or unexpected results.

19. In regards to **claim 9**, claimed material is substantially similar in scope to matter rejected in earlier claim 6 as disclosed by the Heilman and Murakami combination.

20. **Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman in view of Lapeyre et al. (US 4,623,350), hereinafter Lapeyre.**

21. In regards to **claim 11**, Heilman discloses the device of claim 3, except wherein the lower bellows plate extension part is discontinuously formed around an outer circumferential surface of the lower bellows plate. Attention is directed to the secondary reference of Lapeyre, which discloses a total cardiac prosthesis comprising an extra-pericardial pumping unit with a pushing plate extension part (i.e. rod 49) discontinuously formed around an outer circumferential surface of the pushing plate 50 (Col. 17, Lines 29-68; Fig. 11). Heilman and Lapeyre are concerned with the same field of endeavor, namely the design of implantable blood pump actuators. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Heilman by incorporating a pushing plate extension part discontinuously formed around an outer circumferential surface of the pushing plate, as taught by Lapeyre, to utilize the actuation of the motor for oscillation of the pushing plate.

22. **Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman in view of Lapeyre as applied to claim 11 above, and in further view of Dmitruk et al. (SU 816458B), hereinafter Dmitruk.**

23. In regards to **claim 12**, the Heilman and Lapeyre combination discloses of the claim limitations as set forth above in claim 11, except wherein the lower bellows plate comprises two or more discontinuous lower bellows plate extension parts which are arranged at respective positions dividing the lower bellows plate into even sectors. Attention is directed towards the tertiary reference of Dmitruk, which discloses a heat converter for an artificial circulation system wherein the rod 3 (i.e. lower bellows plate extension part) interacts symmetrically with the thrust face 15 (i.e. lower bellows plate) of the blood pump transfer bellows 12, separating the thrust face into two equal sectors as to efficiently depress the bellows (Abstract; Fig. 1 and 2). Heilman, Lapeyre, and Dmitruk are all concerned with the same field of endeavor, namely implantable blood circulation pumps. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the Heilman and Lapeyre combination to incorporate lower bellows plate extension parts which divide the lower bellows plate into even sectors, as taught by Dmitruk, in order to avoid eccentricity or imbalance of the lower bellows plate.

24. In regards to **claim 13**, the Heilman and Lapeyre combination discloses the device of claim 1 and wherein the motor unit comprises a housing at a lower part thereof and is placed below the bellows unit (**Heilman** - Fig. 2, 13, and 14). However, Heilman fails to disclose a bellows guide extension part provided on an edge of the lower bellows plate and extending toward the cam unit, while the housing of the motor unit is provided with a bellows guide to guide the bellows guide extension part. Attention is directed to the tertiary reference of Dmitruk, which discloses a heat converter for an

artificial circulation system wherein the rod 3 (i.e. bellows guide extension part) extends through a sleeve 4 (i.e. bellows guide) and interacts symmetrically with the thrust face 15 (i.e. lower bellows plate) of the blood pump transfer bellows 12. Therefore, as the rod extends through the sleeve while interacting with the thrust face, the bellows deflates and vice-versa (Abstract; Fig. 1 and 2).

25. In regards to **claim 14**, the Heilman, Lapeyre, and Dmitruk combination discloses the device of claim 13 and wherein the bellows guide extension part 3 comprises a rod-shaped part, while the bellows guide 4 comprises a linear bushing (i.e. outer or moving bush 8) to receive the bellows guide extension part therein (**Dmitruk** - Abstract; Fig. 1 and 2).

26. **Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman in view of Faries, Jr. et al. (US 7,238,171), hereinafter Faries.**

27. In regards to **claim 18**, Heilman discloses the device of claim 1, except for further comprising: a pressure regulating unit to regulate pressure in the bellows. Attention is directed towards the secondary reference of Faries which discloses a system for controlling pressurized infusion of intravenous fluids, utilizing a pressure transducer/sensor 88 and controller 36 to regulate the pressure for bellows 20 (Col. 6, Line 53 – Col. 7, Line 6; Fig. 1). Heilman and Faries are concerned with the same field of endeavor, namely systems for controlling the circulation of pressurized fluids utilizing pumps, bellows, and actuators, among other common components. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Heilman by incorporating a pressure regulating unit to regulate pressure in the

bellows, as taught by Faries, in order to maintain the inner pressure of the bellows within a predetermined pressure range.

28. In regards to **claim 19**, the Heilman and Faries combination discloses the device of claim 18 and wherein the pressure regulating unit comprises: a pressure gauge (i.e. Faries' pressure transducer/sensor 88) connected to the bellows (Faries 20) through a pressure connection part (i.e. Faries' hose or tube) and measuring pressure of the fluid in the bellows; a fluid pump (Faries' 86) connected to the pressure connection part and supplying or discharging the fluid to or from the bellows; control valves respectively placed between the bellows and the pressure gauge and between the pressure gauge and the fluid pump and controlling the flow of the fluid; and a pressure control unit (i.e. Faries' controller 36) to control both the control valves and the fluid pump in response to pressure in the bellows measured by the pressure gauge, thus maintaining inner pressure of the bellows within a predetermined pressure range (**Faries** – Col. 6, Line 53 – Col. 7, Line 6, Col. 9, Line 58 – Col. 10, Line 4; Fig. 1).

29. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilman in view of Reinicke (US 4,557,726).**

30. In regards to **claim 20**, Heilman discloses the device of claim 1, except further comprising a diaphragm which communicates with the bellows of the blood pump actuator through a connection part and is deformed according to changes in volume of the bellows, thus pumping blood from the blood pump system to a desired place in the body of a patient according to the deformation of the diaphragm. Attention is directed towards the secondary reference of Reinicke, which discloses an implantable device for

medication dispensing, utilizing a diaphragm which communicates with the bellows 58 of the pump through a connection part 26 and is deformed according to changes in volume of the bellows and medication dispensation (Col. 3, Line 54—Col. 4, Line 29; Fig. 1). Heilman and Reinicke are concerned with the same field of endeavor, namely the design of implantable fluid-pumping systems. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Heilman by incorporating a diaphragm in communication with the bellows of the blood pump actuator, as taught by Reinicke, in order to pump blood from the system to a desired place in the body of a patient.

Response to Arguments

31. **Applicant's arguments filed 27 February 2009 have been fully considered but they are not persuasive.**

32. In the broadest interpretation of the claims, the claims continue to fall within the scope of the listed references considering the articulation and identification of the each element above within the listed references. **Therefore, the rejections made are maintained.**

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremiah T. Kimball whose telephone number is (571)270-7029. The examiner can normally be reached on 8am-6:30pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/J. T. K./
Examiner, Art Unit 3766
June 8, 2009